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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/779,460

01/07/97

GODDIJN

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HM12/1106

EXAMINER

FOX, D

ART UNIT

PAPER NUMBER

1638

DATE MAILED:

11/06/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.

08/779,460

Applicant(s)

Goddijn et al

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- ☒ Responsive to communication(s) filed on 8/2/00
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- ☒ Claim(s) 25, 35-65 is/are pending in the application.
- Of the above claim(s) 37-38, 42, 51-55, 57-58, 63-64 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 25, 35, 36, 39-41, 43-50, 56, 59-62, 65 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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This application has been transferred to Primary Examiner David T. Fox. All future correspondence should be conducted as indicated at the end of this Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants' election in the amendment of 2 August 2000 of Species B, drawn to an antisense RNA-mediated method for inhibiting trehalase, is acknowledged. However, Species A was examined in the last Office action, in response to Applicants' election of Group I on page 6, top paragraph of the preliminary amendment of 12 November 1999, in which Applicants presented new generic claims which encompassed both Group I (chemical trehalase inhibitor) and Group II (antisense RNA trehalase inhibitor). In response to Applicants' arguments in the preliminary amendment of 12 November 1999 that the Restriction Requirement delineating Groups I and II, as set forth during the Personal Interview of 28 October 1999, should be recast as an Election of Species, the Examiner recast the Restriction Requirement as an Election of Species in the last Office action. Applicants' election of Group I in the preliminary amendment of 12 November 1999 was a clear indication that the subject matter of corresponding Species A was intended to be pursued. As stated on page 4 of the last Office action, fourth paragraph, in order to expedite prosecution, the Examiner prosecuted that species corresponding to the previously elected Group, rather than delay prosecution further by sending out a separate Election of Species requirement in response to the newly presented claims. The invitation to elect a species on page 3 of the last Office action, bottom two paragraphs, was merely an invitation for Applicants to

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formally confirm their election of the subject matter of Species A, formerly elected Group I. The remainder of the last Office action consisted of an exhaustive prosecution of the invention of Group I/Species A. The US Patent and Trademark Office does not permit Applicant to shift to another invention once an election is made and has been prosecuted, per MPEP Section 819.

Claim 42 was examined in the last Office action since it appeared to belong to Group I/Species A, as stated on page 11 of the last Office action. The amendment of 2 August 2000 to claim 42 clarifies that it in fact belongs to Group II/Species B. Accordingly, claim 42 has been reassigned to Species B and has been withdrawn from prosecution.

Newly submitted claims 63-64 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: They correspond to previously non-elected Species B, claims 37, 38, 42, 51-55 and 57-58.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 63-64 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim 48 (newly amended) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 is indefinite in its recitation of "the steps of producing trehalose in *plant cells*" (emphasis added) which lacks antecedent basis in claim 35.

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The rejection of the claims under 35 USC 112, first paragraph, has been withdrawn-in-part, in view of Applicants' demonstration in the amendment of 2 August 2000 that other trehalose phosphate synthase genes have been isolated prior to the filing date of the instant invention. In addition, it is now considered that the claims are enabled for any validamycin-type trehalase inhibitor. A modified rejection appears below.

Claims 25, 35-36, 39-41, 43-50, 56, 59-62 and new claim 65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a method for producing trehalose in plants transformed with a gene encoding trehalose phosphate synthase wherein the plants are treated with a chemical trehalase inhibitor comprising validamycin, does not reasonably provide enablement for claims broadly drawn to plants which naturally produce trehalose, the use of any other transgene encoding any other gene product, or the use of non-validamycin chemical trehalase inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last Office action for claims 24-25, 35-36, 39-50, 56 and 59-62.

The rejection of the claims under 35 USC 102(b) over Kendall et al has been withdrawn in view of the amendment to claim 35 of 2 August 2000, and given the failure of the reference to teach whole plant culture following treatment with trehalase inhibitors.

The rejection of the claims under 35 USC 102(a) over WO 95/01446 has been withdrawn in view of the amendment to claim 46 of 2 August 2000, and given the failure of the reference to

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teach treatment with trehalase inhibitors as newly claimed. Claim 47, which previously had this limitation by virtue of its dependence upon claim 44, which depended upon claim 35, should not have been included in this rejection.

The rejection of the claims under 35 USC 103 has been withdrawn, given the unpredictability inherent in the process as discussed above, and the failure of the prior art to teach or suggest the treatment of whole plants, which had been transformed with a gene encoding trehalose phosphate synthase, with chemical trehalase inhibitors, as argued in the amendment of 2 August 2000.

No claim is allowed.

Applicants' arguments filed 2 August 2000 have been fully considered but they are not persuasive with respect to the remaining rejection.

Applicants urge that the enablement rejection is improper, given the Jepson claim format and the permissible omission of that which is well known in the art as set forth in MPEP 2164.01, the lack of undue experimentation required to evaluate other chemical trehalase inhibitors, and the inapplicability of the Examiner's evidence involving genetic manipulation of the more complex starch synthesis pathway.

The Examiner maintains that Applicants' own specification demonstrates that plants which naturally synthesize trehalose are extremely rare, as stated in the last Office action. Furthermore, Kendall et al reinforces this fact, as admitted by Applicants (see, e.g., page 13, bottom paragraph). Thus, plants which naturally produce trehalose are not "well known in the art" within

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the meaning of MPEP 2164.01. The only plant taught by Applicants' specification and Kendall et al to naturally synthesize trehalose, namely "resurrection plant", does not appear to be amenable to topical application of chemicals, due to its waxy coating, and no guidance has been presented in the specification regarding the treatment of this plant.

With regard to the Jepson claim format, MPEP 2129 discusses Jepson claims within the context of analyzing the claims for the purpose of applying prior art, not enablement. While the preamble of claim 35 may encompass a particular enabled species which was known in the prior art, such as a plant transformed with an *E. coli* trehalose phosphate synthase gene as taught by WO 95/01446, the preamble also encompasses a multitude of non-enabled embodiments, namely any plant of any species which produces trehalose by any means including natural ability or transformation with a multitude of genes encoding a multitude of enzymes, which would be required to practice the claimed invention, namely the topical chemical treatment of any plant which produces trehalose by any means.

With regard to the existence and evaluation of other enzymes which can confer trehalose synthesis to plants, and the isolation and evaluation of the corresponding genes, the Examiner maintains that Applicants' allegations that such experiments would not constitute undue experimentation are not deemed probative.

With regard to the literature cited by the Examiner, it is maintained that Applicants' assertions that such art does not apply to a metabolic pathway with the degree of complexity as the trehalose metabolic pathway are not deemed probative. The references provide sound

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evidence that the genetic manipulation of plants for alteration of carbohydrate accumulation is unpredictable.

With regard to Applicants' assertions that the behavior of chemical trehalase inhibitors is not unpredictable, the Examiner maintains that such assertions are contradicted by Applicants' statements on page 14 of the response of 2 August 2000, top paragraph, as well as by the Examiner's detailed analysis set forth on pages 8-10 of the last Office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 9:30AM to 6:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November 2, 2000

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

A handwritten signature in cursive script, appearing to read "David T. Fox", written in black ink.